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 (71) Applicant (for all designated States except US): PFCONSULT OY [FI/FI]; Riippakoivunkuja 5, FIN-Cpoo (FI). (72) Inventors; and (75) Inventors/Applicants (for US only): KARPPANEN Olavi [FI/FI]; Riippakoivunkuja 5, FIN-0213 (FI). KARPPANEN, Pasi, Heikki [FI/FI]; Haahk)2130 E , Heikl 0 Espo	VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, S SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, K MD, RU, TJ, TM), European patent (AT, BE, CH, DE, D ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OA patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, N SN, TD, TG).
4. FIN-00200 Helsinki (FI). KARPPANEN, Pirj Maria, Laelia [FI/FI]; Riippakoivunkuja 5, FI Espoo (FI). NEVALAINEN, Mari, Laelia, Susanna Päivänkilonkuja 6 B 11, FIN-02210 Espoo (FI).	o, Kyl N–0213	li, With international search report. 30
(74) Agent: RUSKA & CO. OY; Runcberginkatu 5, Fli Helsinki (Fl).	N-0010	00
(54) Title: METHOD AND COMPOSITIONS FOR WEIG	GHT C	ONTROL
raised level of the minerals magnesium, calcium and potass	sium. I	nts and food seasoning is disclosed. The ultimate food items contain ngestion of such food items has an advantageous effect on body weignings for use in the preparation of the said food items, and use of such

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METHOD AND COMPOSITIONS FOR WEIGHT CONTROL

FIELD OF THE INVENTION

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The invention relates to the field of weight control. Particularly, the invention relates to the control of obesity by means of certain mineral element nutrients.

BACKGROUND OF THE INVENTION

The intake of various nutrients according to the Recommended Dietary Allowance (RDA, National Research Council, U.S.: Recommended Dietary Allowances. 10th Edition. National Academy Press, Washington, D.C., 1989) is considered to represent the level which guarantees an optimum condition for the maintenance of health. Depending on the gender, age, size, and physiological condition of an individual, the RDA for calcium varies from 0.36 g to 1.2 g, that for magnesium from 0.05 g to 0.45 g, and that for potassium from 0.35 g to 2 g per day. The opinion of the leading experts in the fields of both nutrition and medicine is, that in the industrialized societies, the current concentrations of the mineral element nutrients calcium, magnesium, and potassium in various food items are appropriate to provide these nutrients in the RDA amounts. It is believed that intakes exceeding the RDA are not able to produce any additional beneficial effects as compared with the RDA levels. Quite the contrary, there have been warnings about possible toxic and other harmful effects if the RDA levels are clearly higher than the RDA for prolonged periods of time.

Therefore, these mineral elements are supplemented as a medical therapy in the form of capsules, tablets or solutions only for the correction of existing deficiency in the body or for the prevention of the development of a deficiency which is known to produce various deficiency symptoms or even deficiency diseases. Very seldom foods may be enriched with these nutrients. However, it should be emphasized that the only purpose of any such supplementation is to produce intake levels in accordance with RDA, and/or the prevention or correction of a deficiency of the said nutrients.

Obesity is one of the main risk factors for a number of common and serious diseases of the industrialized populations. Such obesity-associated diseases comprise, for example, high blood pressure with its serious consequences, diabetes, and certain types of cancer. Huge economical and medical efforts are exercised to reduce obesity in various population. Unfortunately, no safe, practical and effective method to be used for the population control of

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obesity is available. In fact, efforts to prevent and decrease overweight have failed in the majority of individuals, and obesity is a continuously increasing problem in most industrialized populations, including USA, Great Britain, Finland and many other countries.

5 SUMMARY OF THE INVENTION

We have now discovered that, contrary to the current knowledge and best medical and nutrition skill, the incorporation of potassium and, in particular, calcium and magnesium in various food items at concentrations which exceed the current levels, produces totally unexpected beneficial effects on obesity which is a state of excessive accumulation of fat tissue in the body.

The present invention provides an effective and practical means to prevent the development of obesity and to decrease existing obesity, and is also able to produce other beneficial effects.

One objective of the invention is to provide a method of producing food seasonings, food ingredients and food items, the method comprising incorporation of at least one of the mineral elements potassium and, in particular, calcium and magnesium, in edible items at appropriately high levels. The ingestion of the ultimate edible food items which, in the presence of their conventional levels of potassium, calcium and magnesium produce and maintain obesity, prevents the development of obesity and even markedly decreases the existing obesity when potassium and calcium and/or magnesium are incorporated according to this invention. Such an effect is surprising and totally unexpected since no weight reducing effect has been ascribed to these mineral elements. The preferable concentrations of magnesium, calcium and potassium in the ultimate food items vary according to the nature of the food item. For the different items prepared according to the method of the present invention, preferable concentrations in weight per cent range from 0-30 for magnesium, 0-30 for calcium and 0-50 for potassium, the highest values applying to the food seasoning which is used as an ingredient in the preparation of the ultimate food items.

Another objective of the invention is to provide a food seasoning which, when used in the method according to the invention, can provide the appropriate levels in the ultimate food items.

EXPERIMENTS DEMONSTRATING THE EFFECTIVENESS OF THE INVENTION

The genetically obese Zucker rat provides a suitable model to examine the effects of various dietary factors or drugs on obesity.

Experiment 1

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In this long-term (8-week) study, 20 obese Zucker rats which had reached an average weight of 465 grams, were divided into two sub-groups of 10 rats each.

- Group 1 received conventional rat chow but common salt (sodium chloride) was incorporated at the level of 6 %, and cholesterol at the level of 1 % of the dry weight of the chow to mimic more closely the human diet. During the 8-week follow-up period the obesity of the rats increased further and the rats reached an average body weight of 520 grams and, hence, the average weight gain was 55 grams (11.8 %). This change was statistically highly significant (p<0.001).
 - Group 2: This group of 10 Zucker rats received a diet which was prepared according to the present invention. The caloric and other content of diet was otherwise exactly the same as in Group 1, but additional magnesium was incorporated at the dietary level of 0.13 %, and additional potassium at the level of 1.57 %. During the 8-week follow-up period the minor weight increase in the average body weight to 472 grams (an average of 7 grams or 1.5 %) was statistically not significant (p>0.1). Hence the diet according to the invention reduced the development of obesity to as little as 12.7 % of that produced by the same diet without the utilization of the invention.
- The diet according to the invention did not significantly (p>0.1) affect the high serum cholesterol level which was 9.7 mmol/l in Group 1 and 10.5 mmol/l in Group 2.

Experiment 2

In this study the effectiveness of the present invention was examined in the Zucker rats

when the rats were clearly obese and had reached an average body weight of 360 grams.

Group 1: The rats received a commercial diet containing all essential nutrients, including adequate levels of the mineral elements sodium, potassium, magnesium, and calcium, to maintain normal body functions. To mimic the current human diets even more closely than in Experiment 1, the diet also comprised 18 % of butter, 1 % of cholesterol and sodium chloride (common salt) at the level of 6 % of the dry weight of the diet.

During the following 2 weeks these 10 control rats receiving the above-mentioned diet reached an average body weight of 390 grams and, hence, gained on the average 30 grams (8 %) additional weight.

- Group 2: This group of 10 Zucker rats received a diet which was prepared according to the present invention. The caloric and other content of diet was otherwise exactly the same as in Group 1, but additional magnesium was incorporated at the dietary level of 0.13 %, calcium at the level of 3 %, and potassium at the level of 1.57 %.
- In the group receiving this diet according to the invention the average body weight was reduced to 325 grams and, hence, the rats lost weight on the average 35 grams (-10 %). Hence, while the body weight was increased by a diet prepared according to the prior art, the diet according to the invention reduced overweight. Overall, the diet according to the invention reduced the body weight by 17 % (325 grams versus 390 grams) as compared to Group 1.

The serum cholesterol level was significantly lowered by the invention (p<0.05). In Group 1 the serum cholesterol level was 10.5 mmol/l but the diet according to the invention lowered it to an average level of 8.3 mmol/l.

25 DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the present invention, as the source of the mineral element nutrients, it is possible to use any physiologically acceptable magnesium, calcium, and potassium compound, as well as magnesium, calcium, and potassium bound in high concentrations naturally or artificially to dietary fibers.

30 Preferable magnesium compounds include, but are not limited to, in particular magnesium sulphate, manesium chloride, magnesium hydroxide, magnesium oxide, and magnesium carbonate, but also many other compounds such as magnesium salts of amino acids, and magnesium salts.

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nesium-rich dietary fibers and other physiologically acceptable magnesium compounds are possible.

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Preferable calcium compounds include, but are not limited to, in particular calcium carbonate, calcium lactate, and calcium chloride, but also many other compounds such as calcium phosphates, calcium sulphate, calcium citrates, calcium tartrate, calcium acetate, calcium propionate, calcium alginate, calcium glutamate, calcium gluconate and other physiologically acceptable calcium compounds are possible.

Preferable potassium compounds include, but are not limited to, in particular potassium 10 chloride, potassium(bi)carbonate, potassium lactate, and potassium sulphates, but also many other potassium compounds such as potassium phosphates, potassium tartrate, potassium acetate, potassium propionate, potassium alginate, potassium gluconate, potassium-rich dietary fibers, and other physiologically acceptable potassium compounds are possible.

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The method in accordance with the present invention can be used for changing the composition of a number of food items, such as, for example, breads, cookies and biscuit-like products, sausages and other meat products, egg foods, dairy products, baby foods, salad dressings, and also for novel seasoning compositions. Seasoning compositions according to the present invention can be used for the seasoning of, for example, such food items as bacon, eggs, miso and other soups, porridge meals, corn flakes, rice flakes, rice cakes, wheat flakes, oat flakes, rye flakes, barley flakes, and various types of "muesli" which are prepared and seasoned according to conventional industrial practices, except that a part or all of the conventional seasonings and salt are replaced by the above described seasoning. In most instances the conventional use of common salt can be largely avoided by the use of the seasonings prepared according to the present invention.

salt in a great variety of other industrially prepared food items as well as in the preparation of foods both in restaurants, catering, home kitchens etc. Such seasonings are particularly

suitable for soups, beefs and other foods in which salty and/or spicy seasonings are used, for the preparation of various food ingredient mixtures, such as, for example, flour or meal and

salt mixtures for the preparation of bread, muesli, corn and rice flakes and breakfast cereal

Seasonings according to the present invention can also be used to replace a part of common

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products. These ingredient mixtures and seasonings, when added to various foods, change their composition in accordance with the present invention. The present invention could also serve as a suitable vehicle for supplementation of phytoestrogens, flavonoids, beta-carotene, vitamins A, D, and E as well as other vitamins, other mineral elements and other beneficial dietary factors, other active ingredients of natural origin, or even drugs.

Example 1. WHITE BREAD

10 A pre-mix is made of the following formulation:

	Sodium chloride	0.60 kg
	Magnesium sulphate (MgSO ₄ ·7H ₂ O)	0.126 kg
	Magnesium hydroxide {Mg(OH) ₂ }	0.020 kg
	Calcium carbonate	0.080 kg
15	Potassium chloride	0.294 kg
	l-lysine hydrochloride	0.021 kg
	Wheat flour	7.500 kg

The following ingredients are added to the pre-mix, and a conventional white bread is made in a conventional commercial baking operation by the straight dough method:

	Wheat flour	30.00 kg
	Vital wheat gluten	0.37 kg
	Promosoy 13 ¹	0.55 kg
	Format ²	0.50 kg
25	Shortening (vegetable oil)	1.12 kg
	Yeast	1.75 kg
	Water	23.75 kg

¹Contains soy protein isolate, non-fat dry milk and emulgators (Engelhardt & Co., Sweden)

²Contains diacetyl tartaric acid esters, CaCO₃ and ascorbic acid with malt flour and sugar

(Ireks Arkady, Germany)

The formulation, containing all the ingredients, is mixed at low speed, dough temperature 27 °C, floor time 30 min, baked in the form of Pullman loaves, fermentation ca. 40 min at 38-40 °C and 80 % relative humidity, baked for 30 min at an oven temperature of 230 °C. This is a good, commercial quality, standard white bread.

Example 2. RYE BREAD

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A pre-mix is made of the following formulation:

	Sodium chloride	0,60 kg
10	Magnesium sulphate (MgSO ₄ 7H ₂ O)	0.126 kg
	Magnesium hydroxide {Mg(OH) ₂ }	0.020 kg
	Calcium carbonate	0.080 kg
	Potassium chloride	0.294 kg
	l-lysine hydrochloride	0.021 kg
15	Rye meal ¹	9.57 kg

The following ingredients are added to the pre-mix, and a conventional sour rye bread is made in a conventional commercial baking operation:

20	Rye meal ¹	20.00 kg
	Vital wheat gluten	0.64 kg
	Coarse rye meal	5.71 kg
	Wheat flour	10.00 kg
	Yeast	0.67 kg
25	Water	33.37 kg

¹Part of rye meal and water are fermented with natural starter overnight, final pH 3.9. The formulation, containing all the ingredients, is mixed for 7 min at low speed, dough temperature 27 °C, dough pH 4.4, floor time 60 min, baked in the form of Pullman loaves, fermentation ca. 40 min at 38-40 °C and 70 % relative humidity, baked for 37 min at an oven temperature of 230 °C.

This is a good, commercial quality, standard sour rye bread.

Preferably, the concentrations by weight of the advantageous mineral elements in the final bread products made by the method according to the present invention are: Mg 0.01-1 %, Ca 0.01 - 1 %, and K 0.1 - 1.5 %.

5 Example 3. MARINADE

A marinade for various types of meats, fish and vegetables is made in a conventional commercial operation from the following formulation:

10	Vegetable oil	0.7680 kg
	Calcium chloride (CaCl ₂ ·6H ₂ O)	0.0023 kg
	Magnesium sulphate (MgSO ₄ 7H ₂ O)	0.0023 kg
	Potassium chloride (KCI)	0.0054 kg
	Sodium chloride (NaCl)	0.0109 kg
15	l-Lysine hydrochloride	0.0004 kg
	Honey	0.0288 kg
	Vinegar (10 weight %)	0.0288 kg
	Spices	0.0096 kg

Calcium chloride, magnesium sulphate, potassium chloride, sodium chloride, l-lysine hydrochloride and honey are mixed with vinegar, and the mixture and the spices are added to the vegetable oil. All the ingredients are mixed thoroughly.

Preferably, the concentrations by weight of the advantageous mineral elements in the final marinades made by the method according to the present invention are: Mg 0 - 1 %, Ca 0 - 1 %, and K 0 - 2.5 %.

Example 4. SEASONING

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A mechanical mixture of the following formulation is made:

30	Calcium carbonate (CaCO ₃)	3.80 kg
	Magnesium sulphate (MgSO ₄ ·7H ₂ O)	0.910 kg
	Potassium chloride (KCl)	2.12 kg

Sodium chloride (NaCl)	4.32 kg
Sodium glutamate	0.40 kg
l-Lysine hydrochloride	0.15 kg
(Spices; optional)	1.00 kg

All the ingredients are mixed thoroughly with a conventional industrial mixer but by taking care that heat is not formed during the process

Preferably, the concentrations by weight of the advantageous mineral elements in the final seasoning made by the method according to the present invention are: Mg 0 - 30 %, Ca 0 - 30 %, and K 0 - 50 %.

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Example 5. SAUSAGE

A pre-mix of the following formulation is made:

	Calcium chloride (CaCl ₂ .6H ₂ O)	0.057 kg
15	Magnesium sulphate (MgSO ₄ 7H ₂ O)	0.057 kg
	Potassium chloride (KCI)	0.132 kg
	Potassium lactate	0.090 kg
	Sodium chloride (NaCl)	0. 27 0 kg
	Sodium lactate	0.090 kg
20	l-Lysine hydrochloride	0.010 kg

This pre-mix is thoroughly mixed with the following ingredients:

	Meat, including natural fat	12.500 kg
	Milk powder	0.840 kg
25	Potato starch	1.160 kg
	Water	6.450 kg
	Sodium nitrite (NaNO ₂ , 10 % solution)	0.030 kg
	Spices	0.085 kg

³⁰ The sausage is processed according to generally known conventional industrial techniques.

Example 6. MINCEMEAT STEAK (HAMBURGER STEAK)

Minced meat 9.67 kg

5 Seasoning of example 4 (with spices) 0.26 kg

The seasoning is mixed with the minced meat. Thereafter the mincemeat steak is prepared according to the processes conventionally used in the preparation of steaks, e.g. for Hamburger restaurants. One serving is a 200 gram steak.

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Example 7. STEAK OF MINCED FISH

Minced fish 9.67 kg

15 Seasoning of example 4 (with spices) 0.26 kg

The seasoning is mixed with the minced fish. Thereafter the steak of minced fish is prepared according to the processes conventionally used in the preparation of steaks for Hamburger restaurants. One serving is a 200 gram steak.

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Example 8. SOY STEAK

Soy protein mixture 9.67 kg
Seasoning of example 4 (with spices) 0.26 kg

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The seasoning is mixed with the soy protein mixture conventionally used for the preparation of soy steaks. Thereafter the steak is prepared according to the processes conventionally used in the preparation of soy steaks. One serving is a 200 gram steak.

Preferably, the concentrations by weight of the advantageous mineral elements in the final sausage or steak products made by the method according to the present invention are: Mg 0.01-1.5 %, Ca 0.01 - 1.5 %, and K 0.1 - 1.5 %.

Exampl 9. MAYONNAISE

	Vegetable oil	0.650 kg
5	Calcium chloride (CaCl ₂ 6H ₂ O)	0.0012 kg
	Magnesium sulphate (MgSO ₄ ·7H ₂ O)	0.0012 kg
	Potassium chloride (KCl)	0.0028 kg
	Sodium chloride (NaCl)	0.0057 kg
	l-Lysine hydrochloride	0.0002 kg
10	Sugar	0.030 kg
	Vinegar (10 weight %)	0.030 kg
	Mustard	0.020 kg
	Water	0.194 kg

15 The mayonnaise is prepared by homogenization by conventional industrial methods.

Example 10. MIXTURE OF VEGETABLE OIL AND BUTTER

20	Vegetable oil	0.350 kg
	Butter	0. 478 kg
	Calcium chloride (CaCl ₂ ·6H ₂ O)	0.0024 kg
	Magnesium sulphate (MgSO ₄ ·7H ₂ O)	0.0024 kg
	Potassium chloride (KCI)	0.0056 kg
25	Sodium chloride (NaCl)	0.0114 kg
	l-Lysine hydrochloride	0.0004 kg

The other ingredients are added to the vegetable oil + butter mixture and mixed according to conventional dairy practice to make the mixture of vegetable oil and butter.

Example 11. SALAD DRESSING

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Vegetable oil	2.0000 kg
Calcium chloride (CaCl ₂ 6H ₂ O)	0.0048 kg
Magnesium sulphate (MgSO ₄ ·7H ₂ O)	0.0048 kg
Potassium chloride (KCl)	0.0112 kg
Sodium chloride (NaCl)	0.0228 kg
l-Lysine hydrochloride	0.0008 kg
Vinegar (10 weight %)	0.1200 kg
Water	1.6360 kg
	Calcium chloride (CaCl ₂ 6H ₂ O) Magnesium sulphate (MgSO ₄ 7H ₂ O) Potassium chloride (KCl) Sodium chloride (NaCl) I-Lysine hydrochloride Vinegar (10 weight %)

The salad dressing is prepared by homogenization by conventional industrial methods.

Preferably, the concentrations by weight of the advantageous mineral elements in the final salad dressing or mayonnaise products made by the method according to the present invention are: Mg 0 - 3 %, Ca 0 - 3 %, and K 0 - 3 %.

15 Example 12. YOGURT

During the preparation of 100 kg of yogurt according to conventional commercial techniques the following ingredients are added and carefully mixed:

20	Magnesium oxide (MgO)	0.225 kg
	Calcium carbonate (CaCO ₃)	0.100 kg
	Potassium lactate	0.300 kg

Preferably, the concentrations by weight of the advantageous mineral elements in the final yogurt made by the method according to the present invention are: Mg 0.1-3 %, Ca 0.1 - 3 %, and K 0.1 - 3 %.

CLAIMS:

- 1. A method of producing food seasoning, food ingredient and/or food item compositions which prevent and decrease obesity, characterized by the addition of at least one mineral element nutrient selected from the group consisting of magnesium, calcium and potassium, so that the final concentration of magnesium is 0 to 30 % by weight, that of calcium is 0 to 30 % by weight, and that of potassium is 0 to 50 % by weight.
- 2. A method according to claim 1, comprising incorporating in a bread, cookie or biscuit-like food item at least one of magnesium, calcium, and potassium in an amount producing in the ultimate edible food item a magnesium concentration by weight of between 0.01 to 1 %, a calcium concentration by weight of between 0.01 to 1 %, and a potassium concentration by weight of between 0.1 to 1.5 %.
- 3. A method according to claim 1 comprising incorporating in a sausage or steak food item at least one of magnesium, calcium, and potassium in an amount producing in the ultimate edible sausage or steak a magnesium concentration by weight of between 0.01 to 1.5 %, a calcium concentration by weight of between 0.01 to 1.5 %, and a potassium concentration by weight of between 0.1 to 1.5 %.

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4. A method according to claim 1 comprising incorporating in a vegetable oil-butter mixture at least one of magnesium, calcium, and potassium, in an amount producing in the ultimate edible vegetable oil-butter mixture a magnesium concentration by weight of between 0 to 0.4 %, a calcium concentration by weight of between 0 to 1 %, and a potassium concentration by weight of between 0 to 1 %.

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5. A method according to claim 1 comprising incorporating in a marinade at least one of magnesium, calcium, and potassium in an amount producing in the ultimate marinade a magnesium concentration by weight of between 0 to 1 %, a calcium concentration by weight of between 0 to 1 %, and a potassium concentration by weight of between 0 to 2.5 ——%.

6. A method according to claim 1 comprising incorporating in a salad dressing at least one of magnesium, calcium, and potassium in an amount producing in the ultimate salad dressing a magnesium concentration by weight of between 0 to 3 %, a calcium concentration by weight of between 0 to 3 %, and a potassium concentration by weight of between 0 to 3 %.

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7. A method according to claim 1 comprising incorporating in a mayonnaise at least one of magnesium, calcium, and potassium in an amount producing in the ultimate mayonnaise a magnesium concentration by weight of between 0 to 3 %, a calcium concentration by weight of between 0 to 3 %, and a potassium concentration by weight of between 0 to 3 %.

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8. A method according to claim 1 comprising incorporating in a yogurt at least one of magnesium, calcium, and potassium in an amount producing in the ultimate yogurt a magnesium concentration by weight of between 0.01 to 3 %, a calcium concentration by weight of between 0.1 to 3 %, and a potassium concentration by weight of between 0.1 to 3 %.

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- 9. A food seasoning, characterized by a magnesium concentration by weight of between 0 to 30 %, a calcium concentration by weight of between 0 to 30 %, and a potassium concentration by weight of between 0 to 50 %.
- 10. Use of a food seasoning according to claim 9 in food items. 20

INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A23L 1/237, A23L 1/304, A61K 33/0 According to International Patent Classification (IPC) or to both n	0 ational classification and IPC	
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed b	y classification symbols)	
IPC6: A23L, A61K		
Documentation searched other than minimum documentation to the	e extent that such documents are included in	n the fields searched
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Electronic data base consulted during the international search (name	e of data base and, where practicable, search	n terms used)
CAPLUS, WPI, EPODOC		İ
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
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X Further documents are listed in the continuation of Bo	x C. X See patent family annex	s.
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9 April 1998 Name and mailing address of the ISA/	Authorized officer	
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Information on patent family members

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